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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,745	11/18/2003	Osman Rathore	VTN 5001CIP	4390

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/715,745	RATHORE ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 November 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/29/07,8/6/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-35 are pending in the application. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Priority

The instant claims 1,9,18,21-26,28 and 29 are afforded the priority date 11/22/02 as the limitations of these claims are found in the provisional application 60/428,620. The instant claims 2-8,10-17,19,20,27 and 30-35 are afforded the priority date 11/18/03 as the limitations of these claims are not found in the provisional application 60/428,620. The elimination to the benefit of priority to the application US 10/028,400 is acknowledged and thus the benefit to the provisional application 60/257,030 is eliminated.

Specification

The amendment to the specification is acknowledged and accepted.

Oath/Declaration

The supplemental oath and declaration is acknowledged and accepted.

Drawings

1. The drawings are objected to because the figures 3,4 and 5 recite "ppm Ag in l ns" on the y axis where there is an **e missing from the word lens**. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if

only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Terminal Disclaimer

2. The terminal disclaimers filed on 12/18/07 disclaiming the terminal portion of any patent granted on this application have been reviewed and are accepted. The terminal disclaimers have been recorded.

New Grounds of Rejection Necessitated by the Amendment

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-4,8-16,19-23 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimai et al. (JP07-270726A) in view of Christ (US 5,843,186) and further in view of Dziabo et al. (US 5,340,583).

5. Shimai et al. (JP07-270726A) discloses a comfortable contact lens containing silver ions and a polymer PMMA (i.e. polymethacrylate) (claims 1,2; p3, [0006-0007]; p4, [0010]) which provides for less bacterial breeding (p4, [0008]; p8, [0034]). The injected amount of silver ions is 1×10^{15} ions/cm^2 and 1×10^{16} ions/cm^2 where there are 0 number of colonies generated (table 1). Shimai et al. does not disclose a silicone polymer, a coating for the polymers or a ligand for binding the silver to the polymer.

6. Christ (US 5,843,186) discloses transparent intraocular lenses that comprises a polymer, such as silicone or PMMA (column 1, lines 42 and 47; column 7, lines 11 and 16; column 8, lines 21-23 and 50-53), a hydrophilic polymer (for coating or impregnation) and an antimicrobial agent, such as silver (column 10, lines 53-56). The hydrophilic material may also act as a coating. The antimicrobial agent, silver, is used in minute quantities and relatively low volume concentrations (column 9, lines 2-15) and will be liberated from the polymer surface and into the surrounding medium (column 6, lines 7-13; column 7, lines 47-50). The foremost advantage of the intraocular lenses of the disclosure is that bactericidal potency is maximized because the metal is guaranteed to go into solution as ions, thus producing a minimum ten-fold reduction in bacterial colonization rate (column 11, lines 34-37).

7. In regards to claim 15, Dziabo et al. (US 5,340,583) discloses ophthalmic devices, such as contact lenses or contact lens cases where the antimicrobial component, such as silver is covalently bound to the polymeric materials (i.e. polysiloxanes) (column 1, lines 8-12; claims 1,5,9 and 10). The antimicrobial component is substantially non-leachable (column 3, lines 9-10) which does convey an amount of leachability. The reactive polymeric material, such as polysiloxanes contains a group/ligand that reacts with the antimicrobial component (column 4, lines 26 and 63+; column 5 lines 1-9).

8. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize contact lenses of silicone-containing or PMMA polymeric material with a coating (Christ) and containing a silver binding ligand to control the release of the silver ions into solution and thus avoid any allergic reactions. The use of PMMA or silicone-containing polymeric material interchangeably is disclosed by Christ and therefore would yield predictable results. The silver releasing compound of the disclosure encompasses that of the instant claims and therefore should have the same properties, such as molar solubility and thus the contact lenses of the disclosure encompass those of the instant claims, should have the same properties and be capable of the same functions, such as providing for a reduction in microbial activity of at least 50, 70 or 90% and not cause argyria.

9. In regards to the initial concentration silver, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as

the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore it would be obvious to alter the initial concentration of silver to maximize the antimicrobial properties of the contact lenses while maintaining a level below which would cause argyria.

10. Claims 1-4,8-14,16-23,25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimai et al. (JP07-270726A) in view of Christ (US 5,843,186) and further in view of Tanaka et al. (US 4,139,513).

11. Shimai et al. (JP07-270726A) discloses a comfortable contact lens containing silver ions and a polymer PMMA (i.e. polymethacrylate) (claims 1,2; p3, [0006-0007]; p4, [0010]) which provides for less bacterial breeding (p4, [0008]; p8, [0034]). The injected amount of silver ions is 1×10^{15} ions/cm^2, 1×10^{16} ions/cm^2 where there are 0 number of colonies (table 1). Shimai et al. does not disclose a silicone polymer, a coating for the polymers or the limitation of continuous wear.

12. Christ (US 5,843,186) discloses a transparent intraocular lenses that comprises a polymer, such as silicone or PMMA (column 1, lines 42 and 47; column 7, lines 11 and 16; column 8, lines 21-23 and 50-53), a hydrophilic polymer (for coating or impregnation) and an antimicrobial agent, such as silver (column 10, lines 53-56). The hydrophilic material may also act as a coating as well as that stated above.

13. Tanaka et al. (US 4,139,513) discloses a copolymer suitable for use in soft contact lenses which can be continuously worn for long term comprising at least one siloxy monomer and a hydrophilic monomer (column 1, lines 64-65; column 2, lines 13 and 44). Silicone rubber contact lenses are unfavorable for use as they have different properties from that of the cornea, thus giving a foreign body sensation (burning), are easily contaminated and are weaker in quality, etc (column 1, lines 24-47). The siloxane bond raises the oxygen permeability but provides a strong water repellent property, thus causing a burning sensation whereas the inclusion of the hydrophilic monomer into the polymer matrix reduces the burning sensation but increases the opacity (column 3, lines 11-33). However, the inclusion of the hydrophilic monomer in the precise amount designated in the disclosure provides for the following advantages, such as the contact lenses of the disclosure can be worn comfortably for about 21 days (column 6, line 13) without giving a foreign body sensation or pain, are colorless/transparent and have excellent oxygen permeability (column 1, lines 14-16 and 66-68; column 3, lines 34-40). No change was observed during a continuous wear experiment which was conducted for 21 days where no change was observed in corneal surfaces and there was no decrease of glycogen. The experiment was conducted for 21 days as it is known that the cycle of metabolism of cornea is about 18 days (column 6, lines 26-27).

14. At the time of the invention it would have been obvious to utilize the copolymeric material of Tanaka et al. that afford continuous wear for contact lenses containing silver antimicrobial agents, such as those of Shimai et al. or Christ as it is inconvenient and

costly to have to change ones contact lenses frequently. One would have a reasonable expectation of success for using the contact lens materials of Tanaka et al. in combination with the antimicrobial contact lenses containing silver of Shimai et al. and Christ to produce an anti-allergy, anti-microbial, comfortable and cost-effective contact lens. The silver releasing compound of the disclosure encompasses that of the instant claims and therefore should have the same properties, such as molar solubility and thus the contact lenses of the disclosure encompass those of the instant claims, should have the same properties and be capable of the same functions, such as providing for a reduction in microbial activity of at least 50, 70 or 90% and not cause argyria.

15. In regards to the initial concentration silver, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore it would be obvious to alter the initial concentration of silver to maximize the antimicrobial properties of the contact lenses while maintaining a level below which would cause argyria.

16. In regards to the number of continuous wear days, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted

that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Although the experiment for continuous wear (Tanaka et al.) was conducted for only 21 days it would be obvious that the extended wear could be for at least 30 days as no changes were observed at 21 days.

17. Claims 1-4,8-14,16 and 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimai et al. (JP07-270726A) in view of Christ (US 5,843,186) and further in view of Maiden et al. (US 6,367,929B1).

18. Shimai et al. (JP07-270726A) discloses a comfortable contact lens containing silver ions and a polymer PMMA (i.e. polymethacrylate) (claims 1,2; p3, [0006-0007]; p4, [0010]) which provides for less bacterial breeding (p4, [0008]; p8, [0034]). The injected amount of silver ions is 1×10^{15} ions/cm^2, 1×10^{16} ions/cm^2 where there are 0 number of colonies (table 1). Shimai et al. does not disclose a silicone polymer (i.e. Balafilcon A or a coating for the polymers.

19. Christ (US 5,843,186) discloses a transparent intraocular lenses that comprises a polymer, such as silicone or PMMA (column 1, lines 42 and 47; column 7, lines 11 and 16; column 8, lines 21-23 and 50-53), a hydrophilic polymer (for coating or impregnation) and an antimicrobial agent, such as silver (column 10, lines 53-56). The hydrophilic material may also act as a coating as well as that stated above.

20. In regards to claim 24, Maiden et al. (US 6,367,929B1) discloses hydrophobic silicone hydrogels suitable for ophthalmic lenses with high oxygen permeability and wettability. The hydrogels comprise a hydrophilic monomer entrapped in a silicone hydrogel monomer matrix (column 2, lines 6-14). The surface of the contact lenses may be coated with a hydrophilic coating to improve the physiological compatibility of the lenses with the surface of the eye (column 5, lines 41-47). The silicone hydrogels of the disclosure have O_2 Dk values for oxygen permeability of between 40 and 300 barrer and are similar to Balafilcon A contact lenses which give a measurement of approximately 79 barrer (column 8, lines 62+; column 9, lines 3-6).

21. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the silicone hydrogel materials of Maiden et al. or Balafilcon A for the preparation of contact lens material containing silver, such as those of Shimai et al. or Christ as the hydrogel materials of Maiden et al. and Balafilcon A are equivalent. The substitution of the silicone hydrogel materials having an increased oxygen permeability and wettability yield predictable results, such as an anti-allergy, anti-microbial and comfortable contact lens. It is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect. The silver releasing compound of the disclosure encompasses that of the instant claims and therefore should have the same properties, such as molar solubility and thus the contact lenses of the disclosure encompass those of the instant claims, should have the same properties and be

capable of the same functions, such as providing for a reduction in microbial activity of at least 50, 70 or 90% and not cause argyria.

22. In regards to the initial concentration silver, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore it would be obvious to alter the initial concentration of silver to maximize the antimicrobial properties of the contact lenses while maintaining a level below which would cause argyria.

23. Claims 1-4,8-14,16,19,20-23 and 25-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimai et al. (JP07-270726A) in view of Christ (US 5,843,186) and further in view of Nissen et al. (*Ophthalmologe* **2000**, *Sept., 97*, 640-643; translation).

24. Shimai et al. (JP07-270726A) discloses a comfortable contact lens containing silver ions and a polymer PMMA (i.e. polymethacrylate) (claims 1,2; p3, [0006-0007]; p4, [0010]) which provides for less bacterial breeding (p4, [0008]; p8, [0034]). The injected amount of silver ions is 1×10^{15} ions/cm^2, 1×10^{16} ions/cm^2 where there are 0 number of colonies (table 1). Shimai et al. does not disclose a silicone polymer, a coating for the polymers or the reduction in microbial colonization of the instant claims.

25. Christ (US 5,843,186) discloses a transparent intraocular lenses that comprises a polymer, such as silicone or PMMA (column 1, lines 42 and 47; column 7, lines 11 and 16; column 8, lines 21-23 and 50-53), a hydrophilic polymer (for coating or impregnation) and an antimicrobial agent, such as silver (column 10, lines 53-56). The hydrophilic material may also act as a coating as well as that stated above.

26. In regards to claims 31-35, Nissen et al. (*Ophthalmologe* **2000**, *Sept., 97*, 640-643; translation) discloses contact lenses provided with a silver layer to provide for antimicrobial action against microbes. The attenuation of the germ load on the silver coated contact lenses was 6 logs in step compared to uncoated lenses for *Pseudomonas aeruginosa* and 1.5 log steps in the case of *Staphylococcus aureus* (p5, results). The silver is present in traces on the lenses and in the concentration range of 50-500 μg/L. When wearing such lenses, argyria which occurs at significantly higher concentrations is not expected (p7, paragraph 3).

27. At the time of the invention it would be obvious to utilize the polymeric materials of Shimai et al. or Christ for the preparation of contact lenses as the use of PMMA or silicone-containing polymeric material interchangeably is disclosed by Christ and therefore would yield predictable results. Shimai et al. and Nissen et al. disclose the reduction of microbial colonization via the use of silver and therefore one would have a reasonable expectation for success for reducing the microbial colonization by at least 6 logs or 1.5 log steps by utilizing silver as the antimicrobial agent (i.e. silver) as disclosed by Nissen et. al. The silver releasing compound of the disclosure encompasses that of the instant claims and therefore should have the same properties, such as molar

solubility and thus the contact lenses of the disclosure encompass those of the instant claims, should have the same properties and be capable of the same functions, such as providing for a reduction in microbial activity of at least 50, 70 or 90% and not cause argyria.

28. In regards to the initial concentration silver, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore it would be obvious to alter the initial concentration of silver to maximize the antimicrobial properties of the contact lenses while maintaining a level below which would cause argyria.

29. Claims 1-4,8-14,16-23 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. (EP1050314A1) in view of Tanaka et al. (US 4,139,513).

30. Barry et al. (EP1050314A1) discloses an antimicrobial and optically clear ocular lens comprising a polymer, such as silicone (column 9, [0043]) and zeolite, containing antimicrobial silver (column 3, [0013]; column 7, [0034-35]), where the lens is resistant to microbial growth in the body or on the surface of the lens (column 3, [0011]; column 5, [0023]). The antimicrobial agent, such as silver (abstract; column 1 [0005]) is incorporated into the lens (abstract; column 4 [0021]; column 5, [0024]) or may be used

as a coating. Silver is particularly safe and nontoxic for the use in contact lenses due to the fact that they are not substantially absorbed into the body and not cause discoloration of the lens over time (abstract; column 9, [0042]). The ion-exchanged silver ions are present in a concentration of about 0.01 to 5 wt% in the zeolite which is included in the polymeric matrix or is in an effective amount to achieve antimicrobial properties (column 3, [00130]; column 4, [0020]). The ion release rate of the silver in the lenses is less than about 100 parts per billion per day (column 8, [0037]). The coating material includes polymers, i.e. hydrophilic polymers, hydrogels, etc. (column 10, [0047]). Barry et al. does not disclose the limitation of continuous wear.

31. Tanaka et al. (US 4,139,513) discloses a copolymer suitable for use in soft contact lenses which can be continuously worn for long term comprising at least one siloxy monomer and a hydrophilic monomer (column 1, lines 64-65; column 2, lines 13 and 44) as well as that stated above.

32. At the time of the invention it would have been obvious to utilize the copolymeric material of Tanaka et al. that affords continuous wear for contact lenses containing silver antimicrobial agents, such as those of Barry et al. as it is inconvenient and costly to have to change ones contact lenses frequently. One would have a reasonable expectation of success for using the contact lens materials of Tanaka et al. in combination with the antimicrobial contact lenses containing silver of Barry et al. to produce an anti-allergy, anti-microbial, comfortable and cost-effective contact lens. The silver releasing compound of the disclosure encompasses that of the instant claims and therefore should have the same properties, such as molar solubility and thus the contact

lenses of the disclosure encompass those of the instant claims, should have the same properties and be capable of the same functions, such as providing for a reduction in microbial activity of at least 50, 70 or 90% and not cause argyria.

33. In regards to the initial concentration silver, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore it would be obvious to alter the initial concentration of silver to maximize the antimicrobial properties of the contact lenses while maintaining a level below which would cause argyria.

34. In regards to the number of continuous wear days, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Although the experiment for continuous wear was conducted for only 21 days it would be obvious that the extended wear could be for at least 30 days as no changes were observed at 21 days.

35. Claims 1-4,8-14,16 and 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. (EP1050314A1) in view of Maiden et al. (US 6,367,929B1).

36. Barry et al. (EP1050314A1) discloses an antimicrobial and optically clear ocular lens comprising a polymer, such as silicone (column 9, [0043]) and zeolite, containing antimicrobial silver (column 3, [0013]; column 7, [0034-35]), where the lens is resistant to microbial growth in the body or on the surface of the lens (column 3, [0011]; column 5, [0023]) as well as that stated above. Barry et al. does not disclose the silicone polymer Balafilcon A.

37. In regards to claim 24, Maiden et al. (US 6,367,929B1) discloses hydrophobic silicone hydrogels suitable for ophthalmic lenses with high oxygen permeability and wettability as well as that stated above.

38. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the silicone hydrogel materials of Maiden et al. or Balafilcon A for the preparation of contact lens material containing silver, such as those of Barry et al. as the hydrogel materials of Maiden et al. and Balafilcon A are equivalent. The substitution of the silicone hydrogel materials having an increased oxygen permeability and wettability yield predictable results, such as an anti-allergy, anti-microbial and comfortable contact lens. It is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect. The silver releasing compound

of the disclosure encompasses that of the instant claims and therefore should have the same properties, such as molar solubility and thus the contact lenses of the disclosure encompass those of the instant claims, should have the same properties and be capable of the same functions, such as providing for a reduction in microbial activity of at least 50, 70 or 90% and not cause argyria.

39. In regards to the initial concentration silver, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore it would be obvious to alter the initial concentration of silver to maximize the antimicrobial properties of the contact lenses while maintaining a level below which would cause argyria.

40. Claims 1-4,8-14,16,19-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. (EP1050314A1) in view of Nissen et al. (*Ophthalmologe* **2000**, *Sept., 97*, 640-643; translation).

41. Barry et al. (EP1050314A1) discloses an antimicrobial and optically clear ocular lens comprising a polymer, such as silicone (column 9, [0043]) and zeolite, containing antimicrobial silver (column 3, [0013]; column 7, [0034-35]), where the lens is resistant to microbial growth in the body or on the surface of the lens (column 3, [0011]; column

5, [0023]) as well as that stated above. Barry et al. does not disclose the reduction in microbial colonization of the instant claims.

42. In regards to claims 31-35, Nissen et al. (*Ophthalmologe* **2000**, *Sept., 97*, 640-643; translation) discloses contact lenses provided with a silver layer to provide for antimicrobial action against microbes. The attenuation of the germ load on the silver coated contact lenses was 6 logs in step compared to uncoated lenses for *Pseudomonas aeruginosa* and 1.5 log steps in the case of *Staphylococcus aureus* (p5, results). The silver is present in traces on the lenses and in the concentration range of 50-500 μg/L. When wearing such lenses, argyria which occurs at significantly higher concentrations is not expected (p7, paragraph 3).

43. At the time of the invention it would be obvious that the antimicrobial silver included in the contact lenses of Barry et al. is capable of reducing the microbial colonization by at least 6 logs or 1.5 log steps by utilizing silver as the antimicrobial agent (i.e. silver) as disclosed by Nissen et. al. as both disclosures are drawn to the same utility, such as using silver in contact lenses as a microbial agent. The silver releasing compound of the disclosure encompasses that of the instant claims and therefore should have the same properties, such as molar solubility and thus the contact lenses of the disclosure encompass those of the instant claims, should have the same properties and be capable of the same functions, such as providing for a reduction in microbial activity of at least 50, 70 or 90% and not cause argyria.

44. In regards to the initial concentration silver, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance

provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore it would be obvious to alter the initial concentration of silver to maximize the antimicrobial properties of the contact lenses while maintaining a level below which would cause argyria.

For all of the rejections above:

45. It is respectfully pointed out that instant claims 1,11,19,20,25 and 28 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Response to Arguments

46. Applicant's arguments filed 12/18/07 have been fully considered but they are not persuasive.

47. Applicant asserts that Shimai et al. does not disclose any details of the test used to evaluate antimicrobial activity, does not disclose how long the antimicrobial efficacy lasts and contains no data from which release rates could be calculated.

48. Shimai et al. does disclose that the known shake flask method/test does provide for antimicrobial effects with the amount of injected silver ions provided (table 1). Also, the instant claims are not drawn to the method of evaluating antimicrobial activity but to ophthalmic devices. The ophthalmic devices of Shimai et al. containing silver encompasses the ophthalmic devices containing silver releasing compound of the instant claims and therefore it would be obvious to optimize the amount of injected silver ions to maximize the antimicrobial efficacy.

49. The combination of references of Shimai et al. and Tanaka et al. teach of ophthalmic devices containing silver for continuous wear (as stated above) and therefore it would be obvious that the use of the siloxy monomer and a hydrophilic monomer copolymers for the preparation of antimicrobial contact lenses containing silver that are anti-allergy, anti-microbial, comfortable and cost-effective.

50. The mathematical calculations necessary for the rate constant calculation of the release of silver from the ophthalmic devices described in the instant claims does not provide patentable limitations to the subject matter of the instant claims

51. Applicant asserts that Christ does not disclose initial ionized silver concentrations.

52. The assertion is moot in view of the new grounds of rejection above.

53. Applicant asserts that Barry et al. discloses an initial concentration of silver ions of 0.01 ppm to 25 ppm.

54. In regards to the initial concentration silver, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore it would be obvious to alter the initial concentration of silver in the contact lenses of Barry et al. to maximize the antimicrobial properties of the contact lenses.

55. Applicant asserts that Tanaka et al. does not disclose or suggest antimicrobial compounds of any kind.

56. The reference of Tanaka et al. was not used to teach of antimicrobial compounds but to teach of ophthalmic devices of siloxy monomer and a hydrophilic monomer copolymers for continuous wear (as stated above) and therefore it would be obvious to include silver as antimicrobial compound of Shimai et al. or Barry et al. in these devices for the preparation of antimicrobial contact lenses containing silver that are anti-allergy, anti-microbial, comfortable and cost-effective.

57. Applicant asserts that Dziabo et al. discloses contact lenses that are substantially silver free, substantially non-leachable antimicrobial component. Antimicrobial components that release from the contact lens are neither disclosed nor suggested.

58. Dziabo et al. does disclose contact lenses where the antimicrobial component, such as silver is covalently bound to the polymeric materials (i.e. polysiloxanes) (column 1, lines 8-12; claims 1,5,9 and 10). The antimicrobial component is substantially non-leachable (column 3, lines 9-10) which does convey an amount of leachability. Therefore the contact lenses of Dziabo et al. contain silver with a degree of leachability.

59. Applicant asserts that Maiden et al. does not disclose or suggest antimicrobial compounds.

60. The reference of Maiden et al. was not used to teach of antimicrobial compounds but to teach of silicone hydrogel ophthalmic lenses with high oxygen permeability and wettability. The silicone hydrogels of the disclosure are similar to Balafilcon A. Therefore, it would be obvious to substitute the silicone hydrogels for Balafilcon A which are compounds that are similar in structure and/of function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect. The ophthalmic lenses/contact lenses of the combined disclosures of Maiden et al. and Barry et al. or Maiden et al. and Christ are drawn to silicone ophthalmic lenses/contact lenses containing silver and the use of Balafilcon A would generate predictable results, such as antimicrobial ophthalmic lenses with high oxygen permeability and wettability.

61. Applicant asserts that Nissen et al. does not disclose the composition of the silver layer or the concentration of silver in the silver layer, report any data relating to the release of silver ions over time or efficacy data beyond 24 hours.

62. The reference of Nissen et al. teaches that the silver is present in traces on the lenses and in the concentration range of 50-500 μg/L.

63. The mathematical calculations necessary for the rate constant calculation of the release of silver from the ophthalmic devices (up to about 1 $days^{-1}$) described in the instant claims does not provide patentable limitations to the subject matter of the instant claims

64. The reference of Nissen et al. teaches that silver present in traces on the lenses in the concentration range of 50-500 μg/L provide for antimicrobial action against microbes (i.e. 6 logs in step compared to uncoated lenses for *Pseudomonas aeruginosa* and 1.5 log steps in the case of *Staphylococcus aureus* (p5, results)). The silver releasing agent of Nissen et al. encompasses the silver releasing compound of the instant claims and therefore it would be obvious to optimize the amount of injected silver ions to maximize the antimicrobial efficacy.

Conclusion

No claims are allowed at this time.

65. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
January 11, 2008

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER